# OsseoGuard®

**Titanium Ridge Augmentation Mesh**
**(Non-Sterile)**

## INSTRUCTIONS FOR USE

### INTRODUCTION
The user of OsseoGuard® Titanium Ridge Augmentation Mesh products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. The manufacturer disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use or installation of OsseoGuard® Titanium Ridge Augmentation Mesh products.

### DESCRIPTION
The OsseoGuard® Titanium Ridge Augmentation Mesh is composed of 0.009 inch thick Titanium (ASTM F-67) in various sizes. The mesh is designed to aid in the reconstruction and augmentation of the alveolar ridge, maxilla, and mandible.

### MATERIAL
CP Titanium (ASTM F-67)

### STERILITY
OsseoGuard® Titanium Ridge Augmentation Mesh is packaged non-sterile. Sterilization should be performed according to standard hospital sterilization procedures for implantable metallic devices. Recommended sterilization procedure is: steam autoclave, pre-vacuum cycle, 270ºF for 15 minutes exposure. Do not exceed 275ºF to avoid compromising functions of polymeric instrumentation.

### CLINICAL INDICATIONS
OsseoGuard® Titanium Ridge Augmentation Mesh is used for stabilization and support of bone grafts in dento-alveolar bony defect sites.

### CONTRAINDICATIONS
OsseoGuard® Titanium Ridge Augmentation Mesh should not be used in the following situations:
- In cases of active or suspected infection.
- Degenerative bone disease which would compromise the implant.
- Insufficient bone at the implant site.
- In patients previously sensitized to titanium.

### WARNINGS
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.

### MAINTAINING DEVICE EFFECTIVENESS
- The surgeon should have specific training, experience, and thorough familiarity with the use of graft stabilization products and techniques.
- The surgeon must exercise reasonable judgment when deciding which mesh and screw type to use for specific indications.
- The OsseoGuard® Titanium Ridge Augmentation Mesh is intended for temporary fixation only until osteogenesis occurs.

### MRI SAFETY INFORMATION
Non-clinical testing has demonstrated that OsseoGuard® Titanium Ridge Augmentation Mesh is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the OsseoGuard® Titanium Ridge Augmentation Mesh is expected to produce a maximum temperature rise of less than 2.3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 3 mm from the implant when imaged with a gradient echo pulse sequence and a 3.0 T MR system.

### PREOPERATIVE CONSIDERATIONS
Soft tissue health in the area of the planned augmentation is of prime importance. Obtaining and maintaining primary closure and healing over the bone graft/mesh complex is critical for predictable results. Local periodontal disease should be controlled by appropriate therapy. At least 12 weeks of healing should elapse between respective surgical procedures and reconstruction augmentation. The surgeon should use his or her individual judgment as to the necessity of tissue expansion procedures.

**INCISION DESIGN AND BONE EXPOSURE**

Chief considerations regarding incision design:

- Incision should be midcrestal if possible since access must be adequate on the buccal and lingual (or palatal) aspect of the defect to be augmented.
- Incision should be planned to allow for expansion of the ridge. Therefore, vertical relief incisions are usually required. These should be made 5 to 10mm away from the site to be augmented. Horizontal releasing incisions, through the periosteum only, are helpful in increasing flap length.
- Mucoperiosteal reflection should be adequate to allow precise placement and fixation of the surgical mesh as well as provide a tension free closure.

**MANAGEMENT OF BONE DEFECT**

- The defect to be augmented should be thoroughly debrided of soft tissue.
- To increase blood supply to the bone graft, a series of perforations should be made in the buccal cortex of the site to be grafted.
- Corticocancellous bone blocks harvested from the mandibular ramus or symphysis are recommended. At this point, the donor blocks are trimmed to fit the defect in such a way as to minimize 'dead space' between the graft and host bone.
- Fixation of the bone graft will be enhanced by the surgical mesh. However, in large grafts primary fixation of the bone graft may be achieved by the use of microfixation screws.
- To prevent soft tissue perforations, it is important that no free edges of the mesh are allowed to contact soft tissue. Use a sufficient number of screws (4 to 6) to ensure fixation of the mesh.

**CAUTION**

- Federal (USA) law restricts the sale, distribution or use of this device to, by or on the order of a licensed practitioner.
- Do not use if package has been opened or damaged prior to use.
- Do not reuse or re-sterilize OsseoGuard® Titanium Ridge Augmentation Mesh.
- Any unused portion that has been exposed to body fluids should always be disposed of properly.
- This device is not to be used in above normal load bearing situations.
- Preoperative and postoperative procedures should always be a consideration of the operating surgeon to insure successful performance of this device.
- OsseoGuard® Titanium Ridge Augmentation Mesh is provided NON-STERILE and must be sterilized prior to implantation

**LABELING SYMBOLS**

Symbols may be used on package labeling for easy identification.

| | |
|---|---|
|  | Manufacturer |
|  | Manufacture Date |
|  | Do Not Reuse |
|  | Caution |
|  | Lot Number |
|  | Catalog Number |
|  | Non-Sterile Product |
|  | Consult Instructions for Use |
|  | MR Conditional |
|  | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or dentist |

Distributed by:
Zimmer Biomet Dental
4555 Riverside Drive
Palm Beach Gardens, FL
33410, USA
+1-561-776-6700
zimmerbiometdental.com

Manufactured by:
Osteogenics Biomedical, Inc.
4620 71st Street, Bldg 78-79
Lubbock, TX 79424 USA



PN2650
Revised 2018-08
Ref: OBI IFU-053